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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,081	07/11/2006	Walid Ali	PHUS040021US2	6958

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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10/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,081	Applicant(s) ALI ET AL.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 13-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060711</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-8 and 13-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/7/2010.
2. Applicant's election without traverse of claims 9-12 in the reply filed on 9/7/2010 is acknowledged.

Claim Objections

3. Claim 10 is objected to because of the following informalities: in line 5, "indicating" should read "indicate". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. In regards to claim 9, "a value of each of the plurality of leads" is vague because a lead does not "have" a value. It is respectfully suggested to recite a memory to store some sort of signal acquired by the leads. Further, a "processor to determine a plurality of convex hulls...and to determine whether a perturbation has occurred" is vague because it is unclear if this recitation is actually placing a structural limitation on the

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"processor" element. If applicant wishes to recite a processor structurally limited to the extent recited, it is respectfully suggested to recite a processor "configured to determine a plurality of convex hulls...and configured to determine whether a perturbation has occurred." As currently recited, the examiner is considering these to be only functional limitations on the processor element, and thus require only a processor *capable* of performing these tasks, if it were programmed in such a way (*i.e.*, a "general purpose" computer).

7. In regards to claim 10, the recitations of "if perturbations exist" (in line 4) and "if a perturbation exists" (in line 6) are vague because it is unclear if this is a condition for the alert signals or not. In other words, the use of "if" allows the alert signal to be output "if" a perturbation exists, but does not preclude the alert signal from being output "if" a perturbation does not exist. It is respectfully suggested to recite "when" instead of "if".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 9-12 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Reisfeld (US 6,633,773, hereinafter "Reisfeld").

10. In regards to claim 9, Reisfeld discloses a plurality of leads, each receiving a monitored signal from a patient (52); a memory to store a value from each of the leads at a plurality of points in time (col. 6, line 62); and a processor capable of being programmed to determine a plurality of convex hulls for a plurality of pairs of signals from the leads, and to determine whether a perturbation has occurred in one or more of the hulls (36). Further, although the claims do not require such, the processor is actually configured to perform these functions, as disclosed at, e.g., col. 2, lines 17-23 (generating a convex hull) and col. 12, lines 42-46 (generating a plurality to determine a perturbation).

11. In regards to claim 10, the apparatus further comprises a user interface (the display) that outputs an alert signal (the image of the heart with associated physiological data alerts the clinician of patient condition) to the user to indicate that a clinically significant change may have occurred in the patient if perturbations exist in a plurality of convex hulls (or if perturbations do not exist in a plurality of convex hulls). In other words, the claim does not require an alert signal only when perturbations exist, or generating an alert signal in response to a determination that perturbations exist.

12. In regards to claims 11 and 12, the apparatus further comprises a display to display each of the plurality of signals from the leads and to display a plurality of plots of each of the signals with respect to the other signals (Figs. 5 and 6; col. 11, line 53 to col. 12, line 42); and overlays a calculated convex hull for each of the plots (i.e., the geometry of the area in question is computed as the convex hull -- Figs. 5 and 6).

13. Claims 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Rudy et al. (US 6,975,900, hereinafter "Rudy").

14. In regards to claim 9, Rudy discloses a plurality of leads, each receiving a monitored signal from a patient (leads connecting electrodes on 12); a memory to store a value from each of the leads at a plurality of points in time (606); and a processor capable of being programmed to determine a plurality of convex hulls for a plurality of pairs of signals from the leads, and to determine whether a perturbation has occurred in one or more of the hulls (24). Further, although the claims do not require such, the processor is actually configured to perform these functions, as disclosed at, *e.g.*, col. 17, lines 4-22 (generating a convex hull) and col. 25, lines 1-14 (generating a plurality to determine a perturbation).

15. In regards to claim 10, the apparatus further comprises a user interface (the display) that outputs an alert signal (the image of the heart with associated physiological data alerts the clinician of patient condition) to the user to indicate that a clinically significant change may have occurred in the patient if perturbations exist in a plurality of convex hulls (or if perturbations do not exist in a plurality of convex hulls). In other words, the claim does not require an alert signal only when perturbations exist, or generating an alert signal in response to a determination that perturbations exist.

16. In regards to claims 11 and 12, the apparatus further comprises a display to display each of the plurality of signals from the leads and to display a plurality of plots of each of the signals with respect to the other signals (28 and Figs. 12-16 and 19-24); and

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overlays a calculated convex hull for each of the plots (i.e., the geometry of the area in question is computed as the convex hull -- Figs. 13A-C).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Primary Examiner, Art Unit 3762